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October 13, 1999

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket No. 99P-1589:
Reply to Purdue October 6, 1999 Submission

Dear Sir or Madam:

The Purdue October 6, 1999 submission made two points. Roxanne responds to those points in reverse order of their presentation.

NDA Data Relevant to Section 505(b)(2) NDA Status

Purdue continues to insist that all data referenced in the labeling of a drug can cause an application to be a Section 505(b)(2) NDA if there is not a right of reference to those data, even if those data are not, in FDA's words, "investigations without which the application could not be approved," 54 Fed. Reg. 28872, 28891 (June 10, 1989). This appears, ultimately, to be the crux of the issue with respect to the Purdue petition.

We have argued previously that the Purdue position is inconsistent with the statute and should be rejected. NDAs do contain "investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use" as described in Section 505(b)(1)(A). They also, however, contain other data. FDA's decision as to whether the labeling submitted in a new drug application is truthful and not misleading is to be "based on a fair evaluation of all material facts," not just on the investigations of safety and effectiveness relied upon for approval, Federal Food, Drug, and Cosmetic Act Section 505(d)(7). An NDA must, accordingly, contain such material facts. Thus, Purdue is wrong in asserting that any data cited in an NDA in support of a labeling statement must be considered to be investigations of the type described in Section 505(b)(1)(A).

One final point should, nevertheless, be made. If FDA were now to change its policy with respect to Section 505(b)(2) to accept Purdue's formulation, the only fair resolution with respect to the Roxane application would be simply to reformulate the

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Roxane labeling to remove the references to Purdue data about which Purdue has expressed a concern. That could be easily done. For example, where Purdue objects to a reference to "published data" on the elimination of oxycodone in patients with end-stage renal failure because of its assertion that the reference is to Purdue data, the labeling could appropriately be modified to say that the drug "should be given with caution" to patients with severe impairment of renal function. That is the statement in the current labeling for FDA-approved Percodan. That labeling clearly does not refer to any Purdue study and is presumably considered by FDA to be appropriate for an approved oxycodone drug.

Roxane reiterates its position that the Purdue interpretation not only is unsupported by the statute but is also bad public policy. The FDA serves the public much better by its traditional position that, once a drug has been shown to be safe and effective by the basic safety and effectiveness investigations submitted in the NDA, all relevant information from any publicly available source may be included in the drug's label.[1]

Purdue's Attack on the FDA's Acceptance of the Roxane Investigations Is Unwarranted

Although its point is of at best tangential relevance to the relief it seeks, Purdue continues to criticize the FDA's conclusion that the studies performed by Roxane show the effectiveness of the Roxane product. FDA's conclusion is, however, supported by the analyses of its reviewers. The FDA medical reviewer concluded that the Roxane product was approvable based on a conclusion that Roxane's studies showed that the sustained release product was "essentially equivalent in efficacy" to the immediate release product. Medical Review of Roxane oxycodone hydrochloride sustained release product dated July 15, 1998, at 85. Purdue focuses on the statistician's review of the effectiveness data for the Roxane product, citing statements out of context and ignoring the statistician's ultimate conclusion. But the FDA statistician, based on his review of the studies at issue, like the medical reviewer recommended that the product should be approved. Statistical Review and Evaluation of Roxane's oxycodone sustained release product, at 22.

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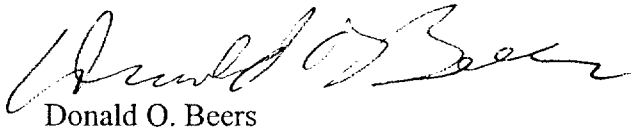
[1] If Purdue's position were to be adopted, FDA would have to abandon class labeling in most contexts.

Purdue's attempt to make an issue out of isolated statements from an FDA review should be disregarded, even if it did have anything to do with the Section 505(b)(2) issue that is addressed in the Purdue petition (as it does not).

Respectfully submitted,



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